K110201

BIOMET
MANUFACTURING CORP.

JUL 2 1 2011

510(k) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92

Submitter Information	
Name	Biomet Manufacturing Corp.
Address	56 East Bell Drive Warsaw, IN 46581-0857
Phone number	(574) 267-6639
Fax number	(574) 371-1027
Establishment Registration Number	1825034
Name of contact person	Patricia Sandborn Beres Senior Regulatory Specialist
Date prepared	January 3, 2011
Name of device	
Trade or proprietary name	ExploR® Radial Head Plating System
Common or usual name	• plate, fixation, bone • screw, fixation, bone
Classification name	• Single/multiple component metallic bone fixation appliances and accessories • Smooth or threaded metallic bone fixation fastener
Classification panel	Orthopedics
Regulation	• 21 CFR 888.3030 • 21 CFR 888.3040
Product Code(s)	• HRS • HWC
Legally marketed device(s) to which equivalence is claimed	K062494 - EBI OptiLock® Upper Extremity Plating System K033456 - EVOLVE® Radial Plate K040777 - Synthes (USA) LCP Radial Head Plating System
Reason for 510(k) submission	New device
Device description	The ExploR® Radial Head Plating System is comprised of 3 styles of plates (neck plates, rim plates and rim long plates) in two sizes (small and standard) each and locking and non-locking screws in multiple lengths. Plate sizing and contouring was developed through the use of Biomet's IntelliFIT Technology which uses contour analysis to map patterns in complex bone on cadaveric specimens to determine plate sizing. (Note, the software was used to determine a set of pre-defined plate sizes and is not used to create individual, patient matched plates.)
Intended use of the device	Bone fixation

Mailing Address:
P.O. Box 587
Warsaw, IN 46581-0587
Toll Free: 800.348.9500
Office: 574.267.6639
Main Fax: 574.267.8137
www.biomet.com

Shipping Address:
56 East Bell Drive
Warsaw, IN 46582

K110201

Indications for use	The ExploR® Radial Head Plating System is indicated for fractures, fracture dislocations, osteotomies and non-unions of the proximal radius.	
Summary of the technological characteristics of the device compared to the predicate		
Characteristic	New Device	Predicate Device*
Plate Design	Neck, Rim and Long Rim	K062494 K033456 K040777
Plate Material	Stainless Steel ASTM F138 or F139	K062494
Plate Dimensions	Length: 18.2mm to 26.2mm Width: 15.2 mm – 16.7mm	K062494 K033456 K040777
Screw Design	Locking and Non-Locking	K062494 K033456 K040777
Screw Material	Stainless Steel ASTM F138 or F139	K062494
Screw Dimensions	Diameter: 2.0mm Length: 10-30mm	K033456 K040777

PERFORMANCE DATA

SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE

Performance Test Summary-New Device

Characteristic	Standard/Test/FDA Guidance	Results Summary
Plate Strength	Engineering Analysis	Meet or exceed predicate

Comparative Performance Information Summary

Characteristic	Requirement	New Device	Predicate Device*
Plate Strength	Meet or exceed predicate	Meet	K062494

SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION

Clinical Performance Data/Information: None

MAGNETIC RESONANCE (MR) ENVIROMENT

Biomet® has performed non-clinical Magnetic Resonance Imaging (MRI) studies on Plating Systems manufactured of 316L Stainless Steel per ASTM F138. These Plating Systems are determined to be MR Conditional in accordance to ASTM F2503-08 Standard Practice for Marking Devices and Other Items for Safety in the Magnetic Resonance Environment. MR Conditional refers to an item that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use.

CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA

No mechanical or clinical testing was necessary for a determination of substantial equivalence. The results of engineering analysis indicated the devices performed within the intended use, did not raise any new safety and efficacy issues and were found to be substantially equivalent to the predicate devices.

*Any statement made in conjunction with this submission regarding and/or a determination of substantial equivalence to any other product is intended only to relate to whether the product can be lawfully marketed without pre-market approval or reclassification and is not intended to be interpreted as an admission or any other type of evidence in patent infringement litigation. [Establishment Registration and Premarket Notification Procedures, Final Regulation, Preamble, August 23, 1977, 42 FR 42520 (Docket No. 76N-0355)]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Biomet Manufacturing Corp.
% Ms. Patricia Beres
Senior Regulatory Specialist
56 East Bell Drive, P.O. Box 587
Warsaw, Indiana 46581-0587

JUL 2 1 2011

Re: K110201
Trade/Device Name: ExploR® Radial Head Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: June 22, 2011
Received: June 24, 2011

Dear Ms. Beres:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110201

Device Name: ExploR® Radial Head Plating System

Indications For Use:

The ExploR® Radial Head Plating System is indicated for fractures, fracture dislocations, osteotomies and non-unions of the proximal radius.

Prescription Use ___X___ AND/OR Over-The-Counter Use __NO___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Mutterer

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110201